

Food and Drug Administration, HHS

§ 189.113

- 189.140 Diethylpyrocarbonate (DEPC).
- 189.145 Dulcin.
- 189.155 Monochloroacetic acid.
- 189.165 Nordihydroguaiaretic acid (NDGA).
- 189.175 P-4000.
- 189.180 Safrole.
- 189.190 Thiourea.
- 189.191 Chlorofluorocarbon propellants.

Subpart C—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

- 189.220 Flectol H.
- 189.240 Lead solders.
- 189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.
- 189.280 4,4'-Methylenebis (2-chloroaniline).
- 189.300 Hydrogenated 4,4'-isopropylidene-diphenolphosphite ester resins.
- 189.301 Tin-coated lead foil capsules for wine bottles.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14659, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 189 appear at 61 FR 14482, Apr. 2, 1996.

Subpart A—General Provisions

§ 189.1 Substances prohibited from use in human food.

(a) The food ingredients listed in this section have been prohibited from use in human food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Use of any of these substances in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully be used in human food. No substance may be used in human food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, pursuant to part

10 of this chapter, and will be published for comment if it contains reasonable grounds.

[42 FR 14659, Mar. 15, 1977, as amended at 54 FR 24899, June 12, 1989]

Subpart B—Substances Generally Prohibited From Direct Addition or Use as Human Food

§ 189.110 Calamus and its derivatives.

(a) Calamus is the dried rhizome of *Acorus calamus* L. It has been used as a flavoring compound, especially as the oil or extract.

(b) Food containing any added calamus, oil of calamus, or extract of calamus is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of May 9, 1968 (33 FR 6967).

(c) The analytical method used for detecting oil of calamus (β -asarone) is in the "Journal of the Association of Official Analytical Chemists," Volume 56, (Number 5), pages 1281 to 1283, September 1973, which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, also from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 47 FR 11855, Mar. 19, 1982; 54 FR 24899, June 12, 1989]

§ 189.113 Cinnamyl anthranilate.

(a) The food additive cinnamyl anthranilate ($C_{16}H_{15}NO_2$, CAS Reg. No. 87-29-6) is the ester of cinnamyl alcohol and anthranilic acid. Cinnamyl anthranilate is a synthetic chemical that has not been identified in natural products at levels detectable by available methodology. It has been used as a flavoring agent in food.

(b) Food containing any added cinnamyl anthranilate is deemed to be adulterated in violation of the act

§ 189.120

based upon an order published in the FEDERAL REGISTER of October 23, 1985.

[50 FR 42932, Oct. 23, 1985]

§ 189.120 Cobaltous salts and its derivatives.

(a) Cobaltous salts are the chemicals, $\text{CoC}_4\text{H}_6\text{O}_4$, CoCl_2 , and CoSO_4 . They have been used in fermented malt beverages as a foam stabilizer and to prevent "gushing."

(b) Food containing any added cobaltous salts is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 12, 1966 (31 FR 8788).

§ 189.130 Coumarin.

(a) Coumarin is the chemical 1,2-benzopyrone, $\text{C}_9\text{H}_6\text{O}_2$. It is found in tonka beans and extract of tonka beans, among other natural sources, and is also synthesized. It has been used as a flavoring compound.

(b) Food containing any added coumarin as such or as a constituent of tonka beans or tonka extract is deemed to be adulterated under the act, based upon an order published in the FEDERAL REGISTER of March 5, 1954 (19 FR 1239).

(c) The analytical methods used for detecting coumarin in food are in sections 19.016-19.024 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 189.135 Cyclamate and its derivatives.

(a) Calcium, sodium, magnesium and potassium salts of cyclohexane sulfamic acid, $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})_2\text{Ca}$, $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})\text{Na}$, $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})_2\text{Mg}$, and $(\text{C}_6\text{H}_{12}\text{NO}_3\text{S})\text{K}$. Cyclamates are synthetic chemicals having a sweet taste 30 to 40 times that of sucrose, are not

21 CFR Ch. I (4-1-98 Edition)

found in natural products at levels detectable by the official methodology, and have been used as artificial sweeteners.

(b) Food containing any added or detectable level of cyclamate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 21, 1969 (34 FR 17063).

(c) The analytical methods used for detecting cyclamate in food are in sections 20.162-20.172 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 189.140 Diethylpyrocarbonate (DEPC).

(a) Diethylpyrocarbonate is the chemical pyrocarbonic acid diethyl ester, $\text{C}_6\text{H}_{10}\text{O}_5$. It is a synthetic chemical not found in natural products at levels detectable by available methodology and has been used as a ferment inhibitor in alcoholic and nonalcoholic beverages.

(b) Food containing any added or detectable level of DEPC is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 2, 1972 (37 FR 15426).

§ 189.145 Dulcin.

(a) Dulcin is the chemical 4-ethoxyphenylurea, $\text{C}_9\text{H}_{12}\text{N}_2\text{O}_2$. It is a synthetic chemical having a sweet taste about 250 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of dulcin is deemed to be adulterated in violation of the act, based upon an order published in the